Otto Bock
ORTHOPEDIC INDUSTRY, INC.

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MAR - 3 2000

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	Otto Bock Orthopedic Industry, Inc.
2.	*Address:*	3000 Xenium Lane North Minneapolis, MN 55441
3.	*Telephone:*	612-553-9464
4.	*Contact Person:*	John Hendrickson
5.	*Date Prepared:*	February 14, 2000
6.	*Registration Number:*	2182293

B. Device

1.	*Name:*	Protegé Wheelchair
2.	*Trade Name:*	Protegé Wheelchair
3.	*Common Name:*	Manual Wheelchair
4.	*Classification Name:*	Manual Wheelchair
5.	*Product Code:*	IOR
6.	*Class:*	I
7.	*Regulation Number:*	890.3850

Otto Bock Orthopedic Industry, Inc.
3000 Xenium Lane North • Minneapolis, MN 55441
Telephone (612) 553-9464 • Toll Free (800) 328-4058
Telefax (612) 519-6150 • Toll Free (800) 962-2549
http://www.ottobock.com • E-Mail: info@ottobock.com

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C. Identification of Legally Marketed Devices

1. *Name:* Zero Gravity Wheelchair
2. *K Number:* K931751
3. *Date Cleared:* July 22, 1993

D. Description of the Device

The Protegé wheelchair is used by handicapped persons with normal activity as a device for rehabilitation. The handicapped person can move the wheelchair by propelling the handrims, which are fixed at the rear wheels. The wheelchair can be steered by different rotation of the rear wheels. The position of the frong wheels automatically follow that movement.

With push handles at the backrest, the wheelchair can be pushed by an assisting person. Using the foot pedals, which are integrated as standard equipment in the frame construction, the assisting person can tip the wheelchair.

The wheelchair is equipped with a holder for elbow crutches and two anti-tip devices, which are adjustable in two lengths.

The Protegé wheelchair is equipped with 24" x 27 mm solid rear tires mounted on plastic rims. The mounted handrims are made of steel. The rear wheels are connected to the frame with M12 screws. The rear wheel can be fixed in six different positions to adjust the wheelbase, the seat height and the center of gravity to the user's needs. The swiveling wheel forks are also fixed with screws. The 6" x 30 mm solid front tires are mounted on one-piece plastic rims. If the rear wheel position is changed, the bearing of the caster wheel fork can be adjusted again to the vertical position.

The wheelchair is foldable and consists of two rigid side frames (aluminum alloy, bent and welded construction) which are connected by a single diagonal strut. The diagonal strut length can be adjusted in three steps.

To stabilize the frame, after unfolding, each seat tube flips into two clips mounted on the upper horizontal frame tubes.

The toggle brake can be adjusted to different rear wheel diameters and tire wear by moving it along the frame tube. Each brake is equipped with a handle extension, which is fixed to the frame with a stretchable tape to prevent loss. The brakes can only be used as parking/emergency brakes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2000

Mr. John Hendrickson
President
Otto Bock Orthopedic Industry, Inc.
3000 Xenium Lane North
Minneapolis, Minnesota 55441

Re: K000602
Trade Name: Protegé Manual Wheelchair
Regulatory Class: I
Product Code: IOR
Dated: February 14, 2000
Received: February 23, 2000

Dear Mr. Hendrickson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: *To be determined*

Device Name: Protegé Manual Wheelchair

Indications for Use:

- Manual transportation device for person who are unable to walk or have a walking impediment.

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR OVER-THE-COUNTER USE X
(optional Form 1-2-96)

NEO for JZD

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000602